

REMARKS

Claims 1-5, 8-10, 13, 14, and 19-23 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,858,154.

Regarding independent claims 1 and 19, and dependent claims 2-5, 8-10, 13 and 14, the Examiner indicates that the '154 patent discloses a method for providing quality control in an analytical instrument. The Examiner specifically indicates that the '154 patent discloses a method that includes the step of "evaluating the instrument analysis data using the control data to determine a functional status of the analytical instrument", and cites Col.3, lines 55-57 of the '154 patent as support. Applicant respectfully disagrees. The passage cited by the Examiner does not appear to be relevant to the step in question. Applicant therefore respectfully requests the Examiner clarify the rejection and indicate the relevancy of the cited passage.

Looking beyond the cited passage, applicant respectfully submits that the methods of amended claims 1 and 19 are novel and not obvious in view of the disclosure of the '154 patent. The '154 patent discloses an invention "for evaluating the accuracy and/or the precision of the performance of at least one apparatus in a pool of like apparatuses with respect to the arithmetic mean accuracy and / or precision of the performance of all of the apparatuses in the pool." (Col.2, Lines 62-67) The '154 patent, therefore, discloses a method that requires interactive communication with a pool of like apparatuses.

Amended claims 1 and 19 recite the step of "performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data to determine a functional status of the analytical instrument". The step as now claimed provides that the evaluation is performed within the analytical instrument using the control data. Consequently, the analysis can be performed anywhere, without connection to other apparatus or a central database. This characteristic provides significant advantages. Point-of-care devices are typically used in a variety of different environments, many of which do not allow for connection to another apparatus or a central database. The present invention allows for quality control procedures without connection to another apparatus or a central database. Another advantage is the ease of administering the quality control procedure. Under the present invention, there is no

connection to another apparatus or a central database. Consequently, the requirement to perform the connection and the possibility for error associated with the connection is eliminated.

In view of the above, applicant respectfully requests that the rejection of method claims 1-5, 8-10, 13, 14, and 19 be withdrawn and claims 1-5, 8-10, 13, 14, and 19 be allowed.

Regarding the apparatus of claim 20, the Examiner indicates that the '154 patent teaches a method for providing quality control in an analytical instrument. Applicant respectfully submits that the quality control system claimed in amended claim 20 is anticipated or obvious in view of the disclosure of the '154 patent.

As stated above, the '154 patent, therefore, discloses a method and an apparatus that requires interactive communication with a pool of like apparatuses. The apparatus of amended claim 20, in contrast, recites a "means for performing an evaluation of the analytical instrument within the analytical instrument using the instrument analysis data and the predetermined characteristic values to determine a functional status of the analytical instrument". Consequently, the apparatus enables is operable to perform a quality control analysis anywhere, without connection to another apparatus or a central database. This significant advantages associated with this ability are described above.

In view of the above, applicant respectfully requests that the rejection of apparatus claims 20-23 be withdrawn and claims 20-23 be allowed.

Claims 1, 19, and 20 are provisionally rejected under the judicially created doctrine of obvious-type double patenting. Applicant respectfully submits that amended claims 1, 19 and 20 are not obvious in view of U.S. Patent No. 6,748,337. The differences and significance of those differences are discussed above. For at least those reasons, applicant requests this provisional rejection be withdrawn.

New claim 24 is added to more clearly claim that which the applicant believes to be the invention.

As applicants have traversed each rejection and objection raised by the Examiner, it is respectfully requested that the Examiner withdraw the stated rejections and objections, allow claims 1-5, 8-10, 13, 14, and 19-24, and pass the present application on to issuance. A check in the amount of \$340.00 is provided herewith in payment of the one-month extension and the fee for the additional independent claim. In the event a fee in excess of the amount provided for in the accompanying check is due, please charge our Deposit Order Account No. 50-3381.

Respectfully submitted,

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